

PCT

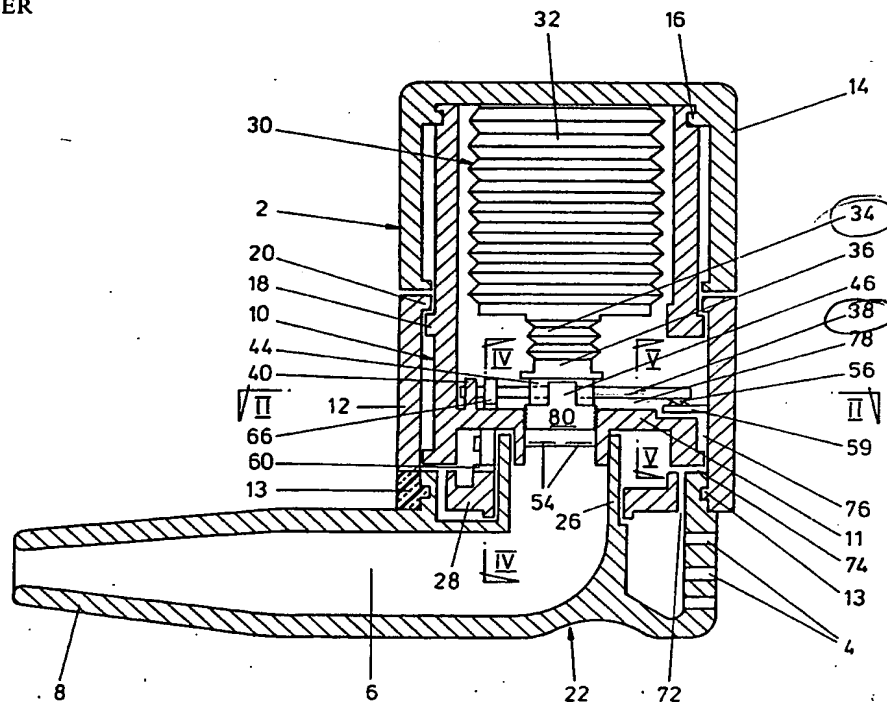
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/GB93/01293 (22) International Filing Date: 15 June 1993 (15.06.93)  (30) Priority data: 9212670.5 15 June 1992 (15.06.92) GB  (71) Applicant (for all designated States except US): NORTON HEALTHCARE LTD. [GB/GB]; Gemini House, Flex Meadow, Harlow, Essex CM19 5TJ (GB).  (72) Inventors; and (75) Inventors/Applicants (for US only) : LANGFORD, Alan, Keith [GB/GB]; 33A Briscoe Road, Hoddesdon, Hertfordshire EN11 9DG (GB). RIDGWAY, Kenneth [GB/GB]; Argyll House, Mole Road, Arborfield, Berkshire RG2 9JQ (GB).			(74) Agent: BROWNE, Robin, Forsythe; Urquhart-Dykes & Lord, Tower House, Merriion Way, Leeds LS2 8PA (GB).  (81) Designated States: AT, AU, BB, BG, BR, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: INHALER



(57) Abstract

An inhaler has a body (2) adapted to receive a collapsible medicament container (30), an air inlet (4) and an outlet (6). A shuttle arrangement (38, 44) is adapted to receive a single dose of medicament from the collapsible container and to transfer the dose to a temporary retainer, the retainer being arranged so that air passes over it as the medicament is inhaled.

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## INHALER

This invention relates to an inhaler used for the inhalation of drugs, particularly, but not exclusively for the treatment of respiratory disorders. The invention is particularly of use for dispensing microfine medicament in a particle size known to be effective for penetration to the deep airways of the lungs.

Inhalers are known which administer a single dose of medicament by first puncturing or rupturing a capsule containing the medicament after which the patient inhales through a mouthpiece of the inhaler so that the medicament is entrained in the air flow to enter the patient's airways.

Other single dose inhalant systems include the use of an aerosol container of the prescribed medicament and this is actuated by pressure on a valve stem to emit a single dose into specially designed passageways in the inhaler body and thence to the patient's airways.

The above known types of inhalers have shortcomings and have proved to be unacceptable in some circumstances and to some patients. In the case of systems using single dose capsules these are necessarily very small and particularly when used by elderly or arthritic patients, are difficult to handle and locate correctly in the inhalers.

It is an object of this invention to provide an inhaler that does not suffer from the above shortcomings, which is simple to operate and capable of administering single doses of medicament from a substantial supply source.

In accordance with the present invention an inhaler has a body adapted to receive a collapsible medicament container, an air inlet and an outlet through which air and entrained medicament may be inhaled by a user, means adapted to receive a single dose of medicament from the collapsible container and further adapted to transfer said dose to a temporary retainer, the retainer being arranged so that the air may pass in use from the inlet to the retainer and to the outlet.

-2-

Use of a collapsible container avoids difficulties which previous inhalers have exhibited due to the presence of moveable components which slide together in use. Such sliding surfaces become fouled and do not run freely. In addition medicament may be entrained between the surfaces and thereby wasted.

In preferred embodiments of the invention the collapsible container includes a bellows. The bellows may have a body portion and a neck portion although alternative configurations may be employed. Use of a bellows affords a simple reliable construction which may be easily pressurised to discharge medicament during inhalation. Use of springs may be avoided.

The means adapted to receive a single dose of medicament may include a first aperture adapted to communicate with the outlet of the collapsible container. Said means may also include an elongate member having a second aperture.

In a preferred embodiment of the invention an inhaler includes a dispensing head having a channel within which the elongate member is disposed, the dispensing head including said first aperture, further including a third aperture and being arranged so that the inhaler is moveable between first and second positions wherein the aperture communicates with the first and third apertures respectively. The dispenser may take the form of a shuttle moveable between configurations wherein the first and third apertures communicate with the second aperture. The shuttle may comprise a sleeve through which the elongate member extends, the sleeve incorporating faces which abut the latter to provide an accurate dose metering arrangement.

The elongate member may comprise a transfer arm.

The elongate member is preferably pivotable in use about an axis adjacent an end thereof between a first position wherein the second aperture communicates with the first aperture and with the outlet of the collapsible container, and a second position wherein the second aperture communicates with the third aperture but not with the outlet of the container.

In preferred embodiments of the invention resilient means

-3-

are adapted to shake medicament from the retainer in use. The resilient means may include a trigger arrangement adapted to suddenly agitate or release the resilient means to shake medicament from the retainer. Such an arrangement has the advantage that adherence of the medicament to the retainer is avoided ensuring accurate dosage and keeping of the moving parts of the shuttle clean. The trigger may be moveable between a cocked position wherein a single dose medicament is retained by the container and a discharge position wherein the dose is shaken from the container.

The resilient means preferably includes the elongate member or transfer arm and the trigger preferably includes a toothed projection or other cam surface arranged to deflect the member as the latter is moved from the first position and further arranged to release the elongate member as the latter is moved to the second position. Alternative overcentre arrangements may be employed.

The inhaler body preferably includes a cylindrical portion adapted to rotate incrementally in use, the cylindrical portion being adapted to engage the elongate member causing movement of the latter between said first and second positions. The inhaler may further comprise a ratchet and pawl arrangement adapted to be actuated by movement of the elongate member between said first and second positions.

In preferred embodiments of the invention flexible reeds are adapted to vibrate as air passes during inhalation, creating an audible signal that medicament has been dispensed.

The ratchet and pawl arrangements may rotate a dosage counter which may be visible, for example through a translucent part of the rotatable cylindrical portion, affording a display of a number of doses available for use.

The invention is further described by means of example but not in any limitative sense, with reference to the accompanying drawings of which:

Figure 1 is a section view of an inhaler according to the invention;

Figure 2 is a second view on the line II - II;

-4-

Figure 3 is a section view on the line III - III of Figure 2 with parts in one position;

Figure 4 is a view similar to Figure 3 but with the parts in a second position;

Figure 5 is a scrap section view on the line V - V of Figure 1;

Figure 6 is a scrap section view on the line VI - VI of Figure 1 of a dosage indicatory system; and

Figure 7 is a view similar to Figure 1 but of an alternative embodiment.

As seen in Figures 1 to 6 of the drawings an inhaler according to the invention comprises a main body 2 having an air inlet 4 and an air outlet 6, the outlet including a mouthpiece 8.

The body comprises an inner cylindrical portion 10 and a cap 14 detachably secured to the inner portion at 16. The attachment may be either by means of an inner annular ridge which is snapped into a mating groove formed in the inner portion, or by means of a quick screw thread.

The inner portion 10 is rotatable within a stationary cylindrical sleeve 12 which is secured at 13 to a lower part 22 of the inhaler. The lower part 22 is formed with the air inlet passages 4 and the air outlet 6 and mouthpiece 8.

The inner cylindrical portion 10 is closed at its lower end by a web 11, and the cylindrical sleeve 12 is provided at part of its lower portion with a translucent or cut away sighting window 15, affording a display of the number of doses available.

The lower part 22 has an upstanding hollow spigot 26 and a dosage indicating disc 28 is freely rotatable about that spigot. The periphery of the disc bears numbers which indicate the number of doses of medicament remaining in a container 30 which is used in conjunction with the inhaler.

The container 30 comprises a main body 32 formed as a bellows, a smaller neck portion 34, also in the form of a bellows, terminating in a coupling tube 36, and a quantity of medicament is provided within the container. Alternative

-5-

bellows arrangements may not include a neck.

As seen particularly in Figures 1 and 2 an elongate member or transfer arm 38 pivoted about a vertical pin 40 projecting upwardly from the web 11, extend diametrically across the web 11 of the inner member 10. The member 38 passes through a slot 42 formed in a dispensing head 44 which is retained laterally between abutments or posts 46 extending upwardly from the web. The dispensing head 44 is thus free to move vertically within the confines of the abutments.

Midway along the length of the elongate member 38 an aperture 48 is provided and the dispensing head 44 is formed with two apertures. A first aperture 50 passes from the top face of the dispensing head 44 to the slot 42, and a second aperture 52, radially offset from the first aperture 50, passes from the slot 42 to the bottom face of the head 44, as shown in Figures 3 and 4. A pair of thin resilient reeds 54 located a short distance below the dispensing head are arranged to emit a musical sound when air passes over them at a predetermined rate.

The end of the elongate member 38 distal from the pivot 40 is formed on this underside as a shallow inverted wedge-shaped projection 56, as shown in Figure 5, and this projection cooperates with one or more notches or teeth 58 on an arcuate plate 59 formed on the inner circumference of the cylindrical sleeve 12. In alternative embodiments of the invention the one or more teeth 58 may be replaced by an alternatively shaped cam formation, for example including a spring, runners or guideways, to afford an overcentre arrangement.

As seen in Figure 6 the peripheral face of the disc 28 is marked with numerals indicative of the number of doses remaining in the container 32 and its upper surface is formed with ratchet teeth 60. These figures are visible through a viewing window 15.

A ratchet lever 62, as shown in Figure 6, is mounted on a horizontal pivot pin 64 and at its upper end is bifurcated at 66 to fit around the sides of the arm 38. A pawl 68, pivoted on a pin 70, is urged by a tension spring 72 to engage the

-6-

ratchet teeth 60. This arrangement ensures unidirectional rotation of the inhaler components.

The lower part of the cylindrical portion 10 and the web 11, and the lower part 22 of the inhaler and the disc 28 are formed to provide airways 72, 74, 76, 78 and 80 leading from the inlet 4 to the reeds 54.

In preparation for use of the inhaler the cap 14 is removed and a loaded bellows container 32 is inserted so that the coupling tube 36 locates against the dispensing head 44. The cap 14 is then replaced, slightly compressing the bellows to retain the container in place.

To prepare a single dose of the medicament for inhalation, the patient rotates the cap 14 and the attached inner portion 10 by a small amount in a clockwise direction as seen from above, and in so doing the projection 56 is engaged by one of the teeth of the notches 58 on the arcuate plate 59. The first effect of this engagement is to rock the arm 38 in an anti-clockwise direction relative to the web 11 so that the aperture 48 in the arm communicates with the aperture 50 in the distributing head or shuttle 44 which in turn is aligned with the aperture in the coupling tube 36. Thus a measured dose of medicament, determined by the volume of the hole 48, is prepared in readiness for inhalation. When the arm 38 engages the side 42A of the slot 42, the projection 56 rides over the tooth 58 causing the arm 38 to move upwardly. This movement causes the distributor head 44 to slide upwardly within the confines of the abutments 46. The coupling tube 36 slightly compresses the neck portion 34 of the bellows container and agitates the powdered medicament contained therein. As the projection 56 follows the profile of the tooth 58 into the next notch the arm, distributor head, coupling tube and bellows all move downwardly again under pressure from the tension in the bellows.

Next, the patient rotates the cylindrical sleeve 12 and the inner portion 10 in an anti-clockwise direction, as seen from above, which causes the projection 56 and notched teeth 58 to first move the arm in a clockwise direction relative to the



-7-

web 11 until the side of the arm abuts the side 42B of the slot 42 in the distributor head, when the aperture charged with its dose of medicament aligns with the aperture 52.

In preferred embodiments the dosage then passes downwardly to fall onto the one or more reeds 54. Further rotation of the sleeve 12 causes the projection 56 to pass over the tooth 58 raising and lower the arm 38, distributor head 44, coupling tube 36 and container neck 34 as before. This shakes free any medicament which may be adhering to the side of the hole 52. Vibration of the reeds during inhalation causes agitation of the medicament disposed on them. This facilitates entrainment of the solid particles in the air flow. The reeds may be laminar or concave. A multiplicity of closely adjacent reeds may form a lattice upon which the medicament can be disposed.

Inhalation by the patient causes ingress of air through the inlet 4, passageways 72, 74, 76, 78 and 80 to vibrate the reeds 54 freeing the medicament from those reeds and entraining the medicament in the air stream to pass through the outlet 6 and mouthpiece 8 into the patient's airways.

In alternative embodiments the dosages may fall onto another surface over which air flow is directed, the reeds being located elsewhere.

It will be clear from Figures 3 and 4 that when the arm is in engagement with the side 42A of the slot 42 medicament is retained temporarily in the aperture 48 by engagement of the bottom face of the arm with the bottom face of the slot. When the arm is moved to its clockwise position with its edge abutting the side 42B of the slot and with the aperture 48 in alignment with the aperture 52, then the aperture 50 which is in alignment with the exit aperture from the coupling tube 36 is obturated by the upper surface of the arm 38.

In an alternative embodiment shown in Figure 7 the bellows type container is supported on inwardly projecting shoulders 102 formed on the inner stationary portion 10 of the body 2, and a spring 104 located within a housing 106 formed in the cap 14 constantly urges the bellows towards a compressed

-8-

condition. Thus any air space in the container which would otherwise be created as the contents are emitted is eliminated, thereby discouraging mixing or de-mixing of the medicament within the bellows.

In a further embodiment, not shown, the bellows is formed initially in a compressed or closed configuration and is then expanded by the forced filling therein by the medicament. The urge or tendency of the bellows to resort to its original compressed state eliminates the need for a compression spring as seen in Figure 7. In this embodiment the closure of the bellows as the medicament is used can be utilized to indicate the quantity of medicament remaining or used by means of a suitable indicator flag and translucent window in the cap 14 and inner portion 10, and in the sleeve 12.

## CLAIMS

1. An inhaler having a body adapted to receive a collapsible medicament container, an air inlet and an outlet through which air and entrained medicament may be inhaled by a user, means adapted to receive a single dose of medicament from the collapsible container and further adapted to transfer said dose to a temporary retainer, the retainer being arranged so that air may pass in use from the inlet to the retainer and to the outlet.

2. An inhaler as claimed in claim 1, wherein the collapsible container includes a bellows.

3. An inhaler as claimed in claim 2, wherein the bellows has a body portion and a neck portion.

4. An inhaler as claimed in any preceding claim, wherein said means adapted to receive a single dose medicament includes a first aperture adapted to communicate with an outlet of the collapsible container.

5. An inhaler as claimed in claim 4, wherein the means adapted to receive a single dose medicament includes an elongate member having a second aperture.

6. An inhaler as claimed in claim 4 or 5, including a dispensing head having a channel within which the elongate member is disposed, the dispensing head including said first aperture and further including a third aperture and being arranged so that the inhaler is moveable between first and second positions wherein the second aperture communicates with the first and third apertures respectively.

7. An inhaler as claimed in claim 5 or 6, wherein the elongate member is pivotable in use about an axis adjacent an end thereof between a first position wherein the second aperture communicates with first aperture and with the outlet of the collapsible container and a second position wherein the second aperture communicates with the third aperture but not with the outlet of the container.

8. An inhaler as claimed in claim 6 or 7, wherein the

-10-

dispensing head includes a shuttle having said first and third apertures.

9. An inhaler as claimed in any preceding claim including resilient means adapted to shake medicament from the retainer in use.

10. An inhaler as claimed in claim 9, including a trigger arrangement adapted to suddenly release said resilient means to shake medicament from the retainer.

11. An inhaler as claimed in claim 10, wherein the trigger is moveable between a cocked position wherein a single dose of medicament is retained by the retainer and a discharge position wherein the dose is shaken from the retainer.

12. An inhaler as claimed in claim 11, wherein the resilient means comprises the elongate member and the trigger includes a toothed projection arranged to deflect the member as the latter is moved from the first position and further arranged to release the elongate member as the latter is moved to the second position.

13. An inhaler as claimed in any of claims 5 to 12, wherein the body includes a cylindrical portion adapted to rotate incrementally in use, the cylindrical portion being arranged to engage the elongate member causing movement of the latter between said first and second positions.

14. An inhaler as claimed in claim 13, having a ratchet and pawl arrangement actuated by movement of the elongate member between said first and second positions.

15. An inhaler as claimed in any preceding claim, including flexible reeds adapted to vibrate as air passes during inhalation.

16. An inhaler having a body adapted to receive a medicament container, an air inlet and an outlet through which air and entrained medicament may be inhaled by a user, means adapted to receive a single dose of medicament from the container and further adapted to transfer said dose to a temporary retainer, the retainer including one or more flexible reeds adapted to vibrate as air passes in use from the inlet to the outlet.

-1/3-

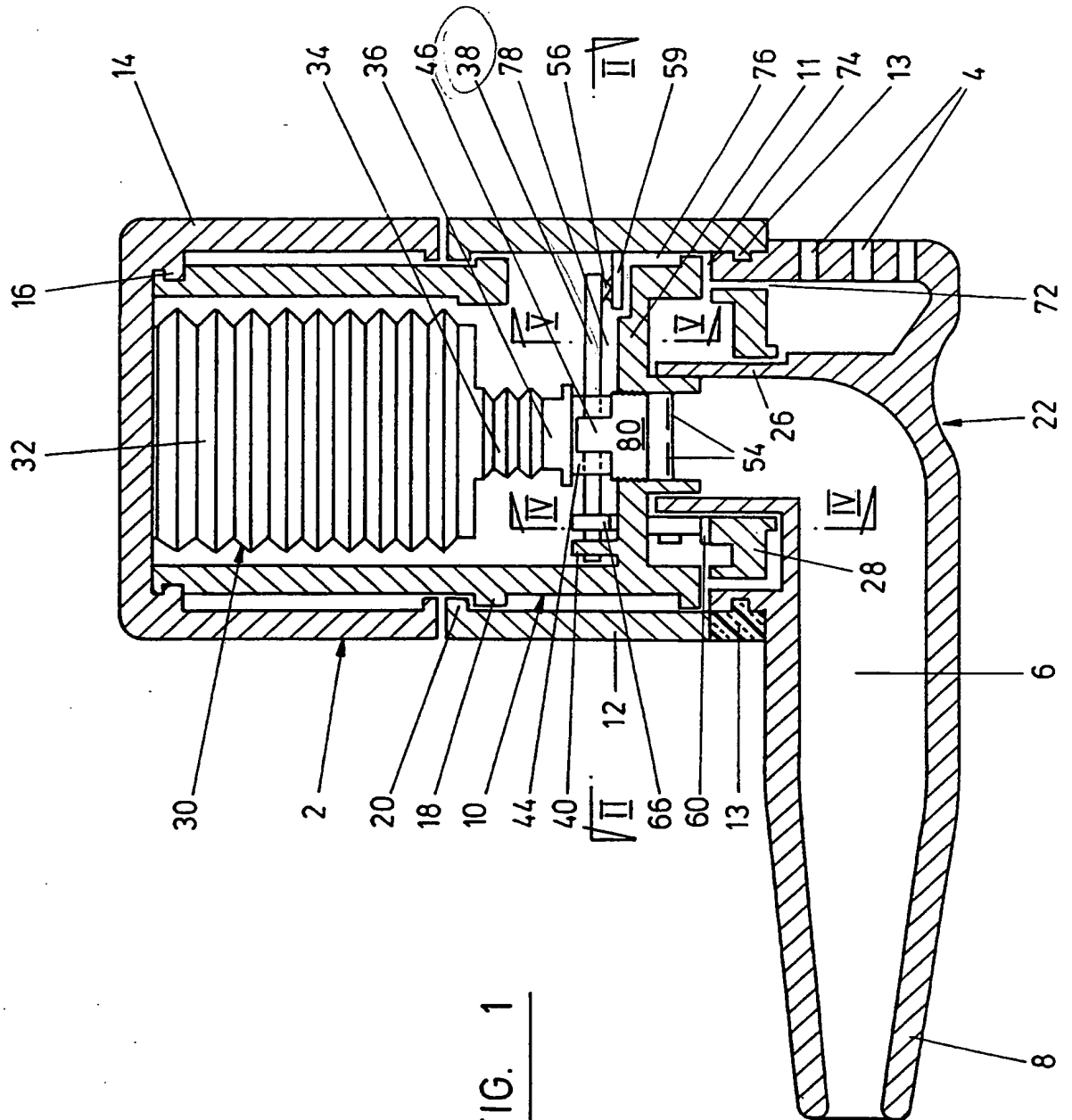


FIG. 1

- 2/3 -

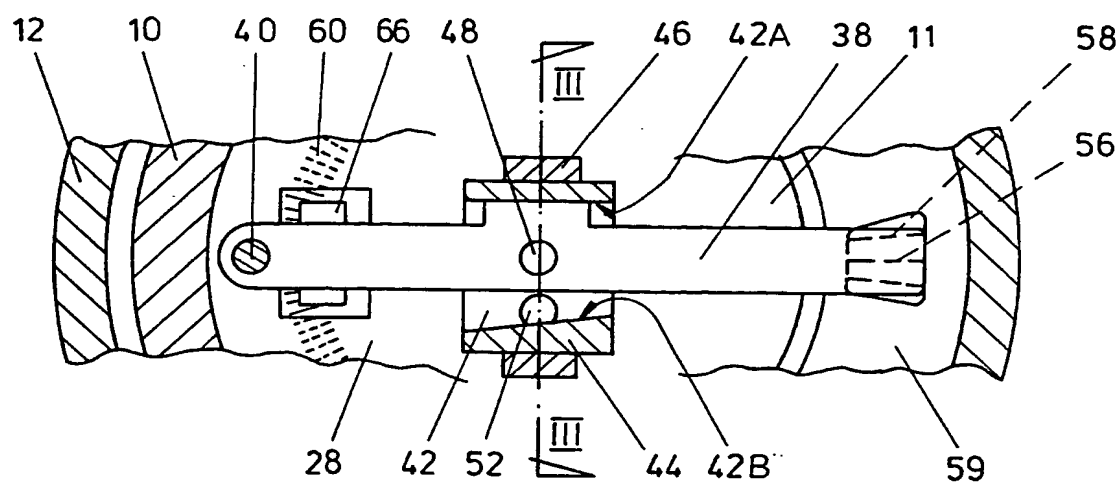


FIG. 2

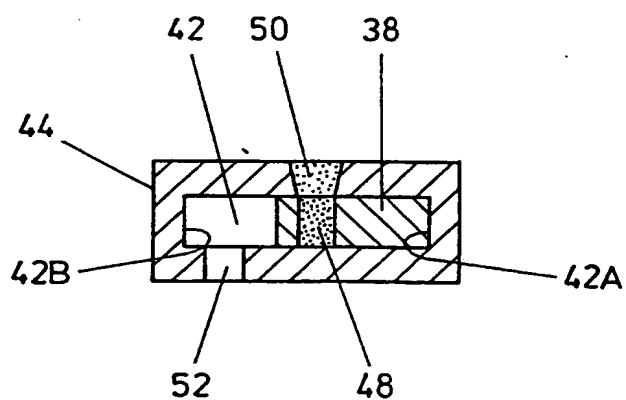


FIG. 3

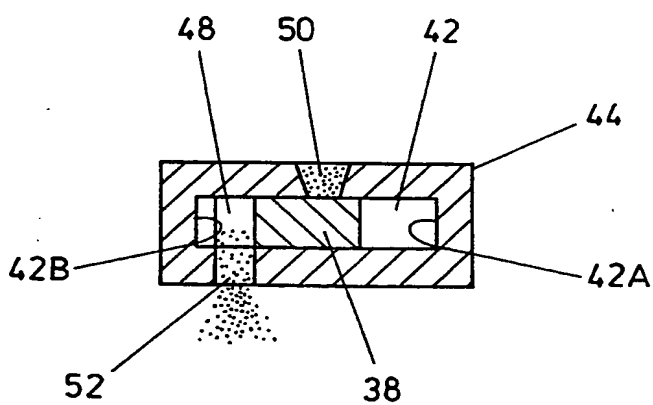


FIG. 4

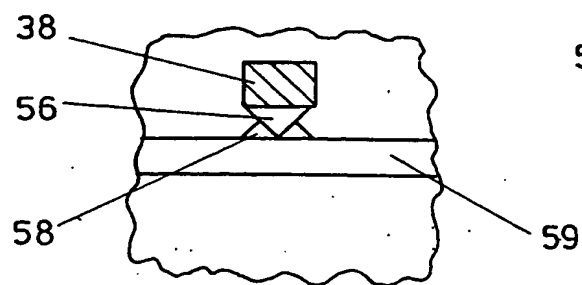


FIG. 5

-3/3-

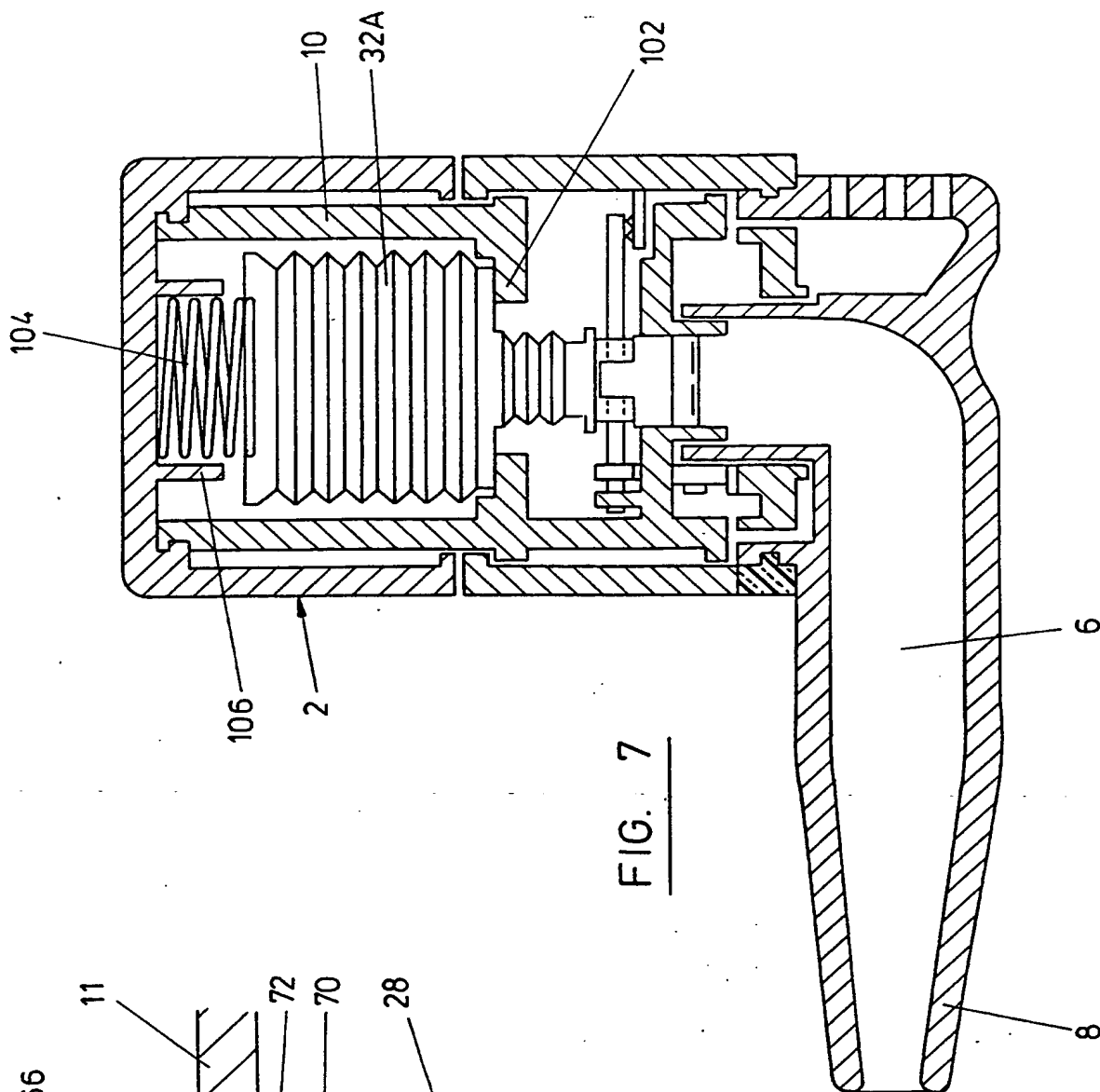


FIG. 7

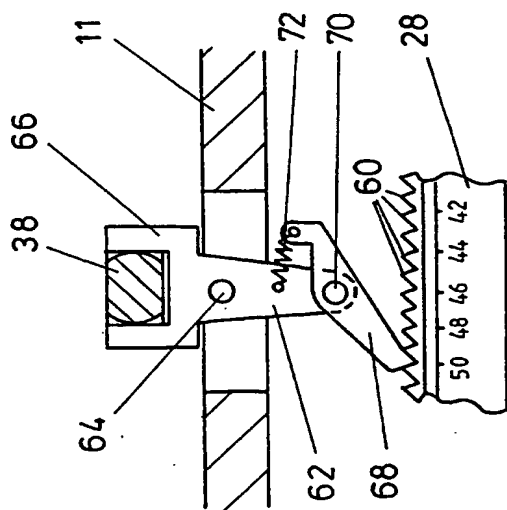


FIG. 6

# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/GB 93/01293

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 5 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC.

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 5 A61M B05B G01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 113 855 (NEWHOUSE) 19 May 1992 see column 4, line 33 - line 68; figures 5,6,8	1,4-6
A	WO,A,88 09680 (POTAK) 15 December 1988 see page 3, paragraph 1 - paragraph 2 see page 5, last paragraph see page 6, last paragraph - page 7, paragraph 1; figure 1	1
A	WO,A,92 04928 (PHARBITA ET AL) 2 April 1992 see abstract; figures 1,2	1
A	WO,A,91 12040 (BIK GULDEN LOMBERG CHEMISCHE FABRIK GMBH) 22 August 1991 see page 3, line 16 - line 24; figure	1
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

\* Special categories of cited documents:

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Date of the actual completion of the international search

15 November 1993

Date of mailing of the international search report

25.11.93

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 93/01293

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 014 814 (SCHERICO LTD.) 3 September 1980 see abstract; figures 1-5 ---	16
A	US,A,3 888 253 (WATT ET AL.) 10 June 1975 see column 3, line 50 - column 4, line 20; figures -----	16

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB93/01293

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

For further information see form PCT/ISA/206 sent on 15/09/93

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Application No

PCT/GB 93/01293

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